UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA, Indictment No.: 20 CR 160 (MKV)

v.

JORGE NAVARRO, et al.,
(SETH FISHMAN and LISA GIANNELLI),

Defendant.

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MEMORANDUM OF LAW IN SUPPORT OF SETH FISHMAN AND LISA GIANNELLI'S MOTION *IN LIMINE*

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I. The Court Should Preclude The Introduction Of Evidence, And Preclude Cross-Examination Of The Defendants, Regarding An Investigation Into The Death Of A Racehorse In Delaware In 2011, Including Reports And An Audio Tape Of An Interview With The Defendants, On The Basis That Any Relevant Evidence Is Substantially Outweighed By The Danger Of Unfair Prejudice

A. The Investigation

According to documents provided by the Government in discovery, on January 5, 2011, Coastal Veterinary Services LLC was contacted to investigate the death of the horse, Louisville, at Nanticoke Racing Stables in Delaware. (USAO_20CR160_00308407). (A copy of the discovery material is annexed hereto as **Exhibit A**).

Upon arriving at the stable, the investigator interviewed the grooms in the barn and was informed that the horse had recently been injected with Pentosan Gold, a product purchased from Lisa M. Ranger (Giannelli), who allegedly sold drugs for Dr. Fishman.

According to the investigator, online research failed to disclose that Dr. Fishman was "appropriately licensed" in the State of Delaware. (*Ibid.*).

On March 31, 2011, the State of Delaware, Division of Professional Regulation received a letter from Benjamin A. Schwartz, an attorney, on behalf of both Lisa Ranger and Dr. Fishman. (Ex. A, USAO_20CR160_00308412-415).

Mr. Schwartz asserted that Dr. Fishman was, indeed, licensed in the State of Delaware. Mr. Schwartz continued that Dr. Fishman maintains a "well developed" relationship with the owners of the horse and was familiar with all the horses in the stable. And, Mr. Schwartz added that Dr. Fishman physically examined all animals that he treated. Mr. Schwartz further

responded that Ms. Ranger functioned as an Administrative Assistant in Dr. Fishman's business, Equestology. According to Mr. Schwartz, Ms. Ranger coordinated Dr. Fishman's visits and teleconferences with clients and the delivery of products and medications prescribed by Dr. Fishman.

Mr. Schwartz explained that Pentosan Gold is manufactured by a company called NatureVet. He described the ingredients and asserted that the substance "is not FDA-regulated because it is a supplement." Mr. Schwartz added that the prescribed use was a "generally acceptable off-label use in this industry." The letter concluded that because there were no violations of the laws or regulations governing veterinarians, the Complaint should be dismissed.

Dr. Fishman and Lisa Giannelli were interviewed by Investigator Will Smith on July 3, 2012 (Ex. A, USAO_20CR160_00308438). The interview was recorded by their attorney. The Government subsequently obtained an audiotape of the interview.

With regard to Dr. Fishman's professional relationship with this stable, Dr. Fishman responded to questions by indicating that he maintains an appropriate professional relationship with each and every equine client he has in Delaware. Dr. Fishman added that he examines each and every animal for whom he prescribes medicine at least once every 365 days. Both Dr. Fishman and Ms. Ranger denied that she ever drew blood from a horse as part of treatment administered on Dr. Fishman's behalf.

Dr. Fishman stated that he prescribed the Pentosan Gold as part of systemic joint therapy for the horse.

Finally, Dr. Fishman stated that he was unaware of Ms. Ranger selling any unprescribed medicine off the back of her truck to horsemen.

On March 15, 2013, the Complaint was dismissed based on insufficient evidence. (Ex. A, USAO_20CR160_003088432).

B. The Applicable Law

Fed.R.Evid. Rule 403 states, in relevant part:

> The Court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

At trial, the evidence will demonstrate that in 2011, Dr. Fishman was, in fact, licensed to practice veterinary medicine in the State of Delaware. While he did not maintain the "racetrack" license that regulated the presence of individuals at the barn during the racing season, his veterinary license authorized him to prescribe medication for horses.

There was no evidence to demonstrate that the death of Louisville was caused by the Pentosan Gold recommended as part of systemic joint therapy by Dr. Fishman. To the contrary, the investigation failed to unearth evidence to dispel the suspicion of investigators that the death of Louisville was the result of an inadvertent injection of a substance into the artery of the racehorse.

Dr. Fishman cooperated with the investigation and participated in an interview. In contrast, the owners and trainers of Louisville did not permit a full autopsy of the racehorse which would have resolved the issue of whether or not the horse was victim to an intra-arterial injection.

Thus, while evidence of the investigation, and Dr. Fishman's statements, may establish that Dr. Fishman's business, Equestology, distributed Pentosan Gold, the relevance of this evidence will be substantially outweighed by the danger of unfair prejudice resulting from the

death of the equine due, in all likelihood, to causes other than any product distributed by Dr. Fishman. The admission of evidence regarding the alleged distribution of Pentosan Gold to this racehorse will prompt a mini-trial on the cause of death of this racehorse; and the culpability of these defendants which will confuse the jury and distract them from the issues in this case. Under these circumstances, any inquiry into defendants' involvement in this investigation should be prohibited.

Should the Court any testimony on this subject, the defendants should be permitted to elicit the fact that the Complaint in this case was ultimately dismissed.

Furthermore, if either Defendant chooses to testify, cross-examination regarding this incident should be precluded for the same FRE 403 reasons stated above, and also under FRE 609 as there was no criminal conviction.

II. Three Categories Of Proffered "Other Crimes" Evidence Should Be Precluded Under The Test Set Forth In *Huddleston v. United States*

In *Huddleston v. United States*, 485 U.S. 681 (1988), the Supreme Court adopted a four part test for determining whether a district court properly admitted "other crimes evidence" in accordance with Fed.R.Evid. Rule 404(b). Under *Huddleston*:

> [T]o determine whether a district court properly admitted other act evidence, the reviewing court considers whether (1) it was offered for a proper purpose; (2) it was relevant to a material issue in dispute; (3) its probative value is substantially outweighed by its prejudicial effect; and (4) the trial court gave an appropriate limiting instruction to the jury if so requested by the defendant. *See United States v. LaFlam*, 369 F.3d at 556.

In *United States v. Scott*, 677 F.3d 72 (2d Cir. 2012), this Circuit ruled that Rule 404(b) and the *Huddleston* test apply to non-criminal acts. Moreover, while *Huddleston* adopts an inclusionary approach, the proffered evidence cannot amount merely to "propensity evidence in sheep's clothing." *See United States v. McCallum*, 584 F.3d 471, 477 (2d Cir. 2009).

With this in mind, we review three categories of proffered 404(b) evidence:

A. The Court Should Preclude Evidence Regarding The Defendant's Manufacture And Export Of Products To The United Arab Emirates

In the Government's letter dated November 17, 2021, providing notice of its intent to offer evidence under Rule 404(b), it alleges that the Presidential Affairs Department, Sector of Scientific Centers and Presidential Camel Department ("Presidential Affairs Department"), "solicited Seth Fishman to distribute performance enhancing drugs and to create and distribute other illegal drugs." (A copy of the letter is annexed hereto as **Exhibit B**).

However, the Government fails to describe any instance in which the products exported for use by the Presidential Affairs Department were "illegal;" or constituted performance enhancing drugs. Moreover, the legality of these transactions fell under the "export exemption" to the statutes governing the allegations in the instant Indictment. *See* F.F.D.C.A. § 801(e).

Thus, the allegation that "Bengawi" solicited the defendant to "create and distribute illegal drugs" is a conclusion of law without any basis in fact. Any probative value of this evidence is substantially outweighed by its prejudicial effect and the likelihood that it will confuse the jury by prompting an examination of the particulars of the export exemption. *See* Fed.R.Evid. Rule 403. At the very least, the Government should be required to set forth, in detail, the manner in which these shipments allegedly ran afoul of the export exemption.

B. The Court Should Preclude Evidence Of An Attempt By "Bengawi" To Engage In Criminal Conduct

The Government then alleges that the defendant was involved in an effort by "Bengawi" to solicit from the defendant a substance intended for use in spiking a woman's unattended drink, *i.e.*, a "Viagra for ladies." The Government alleges that the defendant responded to the request with an offer to make "BI-AGRA" which he described as "female Viagra it makes the woman

bisexual." It is unclear whether the defendant was responding in a humorous vein; or even taking the request seriously. There is no indication that the defendant subsequently shipped a substance intended for this use.

The proffered evidence does not meet the requirements of Fed.R.Evid. Rule 403 that the evidence must offered for a proper purpose, that it must be relevant to a material issue in dispute, and its probative value – if any – is not substantially outweighed by its prejudicial effect. This reference to conduct by "Bengawi" is inadmissible under Rule 403.

C. The Court Should Preclude The Introduction Of Evidence Regarding Allegedly False Descriptions Made By "Bengawi" Filed In An Application Pursuant To Rule 41(g) Seeking The Return Of Property Seized From The Defendant

A third category of evidence relates to allegations that, following the search of the defendant's home and place of business in South Florida, "Bengawi," on behalf of the Presidential Affairs Department, filed an application pursuant to Fed.R.Crim.P. Rule 41(g) in which Petitioners sought through "false descriptions" to compel the Government to return alleged contraband seized from Equestology's office and storage space.

The proffer lacks any evidence that the defendant was a participant in the creation of the allegedly false account; let alone, an explanation of the manner in which the "descriptions" were "false."

The Government has failed to describe the manner in which such evidence would be probative of any relevant issue in this case, leaving the jury to infer that the defendant's association with "Bengawi" makes him a bad actor. This is precisely the "propensity evidence in sheep's clothing" inference prohibited by the cases.

In response to the 41(g) motion by Presidential Affairs as Intervenor, the Government took the position that Petitioner lacked standing to bring the application; and, that the items

seized were, in any event, contraband. Notably, the Government did not allege that statements contained in Petitioner's Rule 41(g) application were false.

Accordingly, the Court should preclude the introduction of this evidence. In the alternative, the Court should reserve decision; and, require the Government to provide a more detailed proffer regarding the probative value of this evidence.

III. The Government Should Be Precluded From Offering Evidence Obtained From The Defendant Pursuant To A Limited Grant Of Immunity

A. Statements Made By The Defendant During His Preparation To Testify At The Trial Of David Brooks

In its 404(b) notice, the Government references information provided by the defendant while he was being prepared to testify as a Government witness at the trial of David Brooks. It is our understanding that the Government's initial interview with Dr. Fishman was covered by the standard grant of limited immunity offered potential witnesses in the Eastern District of New York. (A copy of the Proffer Agreement is annexed hereto as **Exhibit C**).

B. Statements Offered By The Defendant To The Government In This Case Pursuant To A Limited Grant Of Immunity In This Case Should Be Precluded

Shortly after the defendant was charged in the Complaint in the instant case, prior counsel sought to convince the Government to grant the defendant a deferred prosecution. In support of this application, the defendant submitted to approximately 9 hours of questioning. These proffer sessions were subject to the Government's standard limited grant of immunity. (A copy of the Proffer Agreement is annexed hereto **Exhibit D**).

Before the Government is permitted to offer any of the defendant's statements made during the course of these proffer sessions, the Government should be required to provide prior notice of the content of the alleged statement and the basis upon which the Government contends

that the statement is admissible notwithstanding the limitations imposed by the proffer agreement.

IV. The Court Should Preclude The Introduction Of Certain Expert Testimony By Three Doctors Of Veterinary Medicine That The Government Intends To Call As Witnesses

A. The Applicable Law

In *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579, 113 S.Ct. 2786 (1993), the United States Supreme Court issued its watershed opinion to finding the standard for admitting expert scientific testimony in a federal trial.

At the outset, the Court pointed to the express language in Fed.R.Evid. Rule 702. The rule, governing the admission of expert testimony provides:

> If scientific, technical, or other specialized knowledge will assist the trier-of-fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

Id. at 588.

The Court noted that Rule 702 contemplates that the subjects and theories about which an expert may testify are limited in two respects: First, the rule requires that the opinion testimony be the product of "scientific, technical, or other specialized knowledge." Second, the testimony must assist the "trier-of-fact to understand the evidence or to determine a fact in issue." *Id.* at 589. This second limitation goes primarily to the matter of relevance. "Expert testimony which does not relate to any issue in the case is not relevant and, *ergo*, is non-helpful." *Id.* 591. An additional consideration under Rule 702 – and another aspect of relevancy – is whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute. *Ibid.*

In *Daubert*, the Court noted that, when faced with a proffer of expert scientific testimony, (1) the trial judge must determine at the outset, pursuant to Rule 104(a) whether the proffered testimony meets the standard of "scientific" evidence; and (2) whether it will assist the trier-of-fact to understand or determine a fact in issue. As the Court stated:

> This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and [of] whether that reasoning or methodology properly can be applied to the facts in issue.

Id. at 592.

The Court summarized this portion of the holding as follows:

> […] the Rules of Evidence – especially Rule 702 – do assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand.

Id. at 597.

In *Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 137 (1999), the Court held that this gatekeeping obligation applies not only to testimony based on scientific knowledge but also to testimony based on "technical" and other "specialized" knowledge, *citing* Fed.R.Evid. Rule 702. *See Kumho* at 147.

The Court further described the type of testimony that is subject to the Court's gatekeeping function, as well as the requirements of Rule 702 in these words:

> […] whether their specific expert testimony focuses upon specialized observations, the specialized translation of those observations into a theory, a specialized theory itself, or the application of such theory in a particular case, the expert's testimony will often rest 'upon an experience confessedly foreign in kind to the jury's own.'

Id. at 149 *quoting* Learned Hand, *Historical and Practical Considerations Involving Expert Testimony,* 15 Harv.L.Rev. 40, 54 (1941).

B. The Testimony Proffered By The Government

The Government has provided, by letter dated November 18, 2021, notice of its intent to call three witnesses to provide what we contend to be expert testimony relating to the products allegedly distributed by Dr. Fishman. (A copy of the Government's Expert Witness Notice is annexed hereto **Exhibit E**).

The witnesses shall be discussed in turn:

1. Jean Bowman

Dr. Bowman is described as a veterinary medical officer in the Division of Surveillance in the Office of Surveillance and Compliance in the Food and Drug Administration's Center for Veterinary Medicine. According to the Notice, "Dr. Bowman's work involves numerous aspects of unapproved new animal drug matters, including labeling reviews, risk assessments, imports and enforcement actions." *Id.*

The defendant acknowledges that some testimony in the following areas is appropriate:

> The requisite information and data that must be submitted to the FDA in a new animal drug application (NADA) to support FDA Marketing approval.
>
> Searches of public and internal FDA databases reveal no approved NADAs, ANADAs, conditional new animal drug applications (CNADA) or investigation new animal drug applications (INADAs), nor any index listings, for defendant's equine products.

While we acknowledge that some testimony regarding the procedure for approving new animal drug applications is relevant and admissible, the evidence should be limited in scope in order to ensure that its relevance substantially outweighs the likelihood that it will inflame the jury and prejudice the defendant. *See* Fed.R.Evid. Rule 403.

Two areas of proposed expert testimony must be precluded. First, the Court should preclude testimony suggesting that the purpose of the statutory scheme is to ensure the wellbeing of the racehorses. At the end of the case, the jury will be instructed regarding the elements of the adulteration and misbranding statute which is at the core of this prosecution. Throughout the trial, the jury will also be admonished to "follow the law." Opinion evidence regarding the importance of the statute is neither relevant nor probative of the contested issues at this trial. *Compare* 21 U.S.C. §331 and §333(a)(2).

Second, the Court should preclude evidence regarding the "safety and efficacy" of those products allegedly manufactured and distributed by Dr. Fishman. The defendant is not charged in the instant Indictment with crimes relating to the manufacture or distribution of substances that are unsafe for use by animals.

Opinion evidence regarding the "safety and efficacy" of Dr. Fishman's products is, therefore, not relevant to the issues at trial. Moreover, the introduction of such testimony clearly runs the risk of confusing the issues and prejudicing the jury with inflammatory evidence regarding the danger of veterinary use of unapproved drugs. Such testimony would be akin to permitting, in the garden-variety case charging a defendant with the distribution of a controlled substance, opinion testimony by an expert witness regarding the dangers of such proscribed substances as heroin, cocaine, or fentanyl.

2. Diana Link

Dr. Link is described as a veterinary medical officer Master Reviewer at the FDA Center for Veterinary Medicine. According to the Government's notice, Dr. Link "identifies and assesses unapproved new animal drugs as defined under the Food Drug and Cosmetic Act

including through analysis of FDA approval status, prescription status, and illegal extra-label drug use […].” *Id.*

The Government argues that testimony by Dr. Link would not constitute expert testimony, claiming to provide notice that she will testify “out of abundance of caution.” Yet, the description of the areas about which she is anticipated to testify includes, not only her observations of the products that were seized during the search of Dr. Fishman’s premises; but also, the “basis for her determination that such drugs were adulterated and misbranded based on her experience and knowledge of FDA regulations governing animal drugs.” Such testimony would clearly entail an expert opinion. *See Kumho Tire, supra.*

Any such testimony must be limited to information acquired from recognized sources regarding the analysis and content of the substances contained in the various products. It must also avoid the ultimate legal conclusion that either the content of these products or the method of labeling them violated the statutory proscription of adulteration and misbranding. *See United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991).

3. Cynthia Cole

The Government, not content to rely upon the testimony of two experts on matters relating to FDA regulations, proffers, in addition, testimony by Dr. Cynthia Cole. Dr. Cole is a licensed veterinarian, Board Certified in Pharmacology and the Director of the Racing Laboratory at the University of Florida. She was responsible for the regimen of drug testing at the Florida Department of Pari-Mutuel Wagering.

The Government fails to provide even a cursory description of the subjects upon which it seeks to obtain opinion testimony from Dr. Cole. Instead, the Government refers to materials

previously provided to counsel as 3500 material. It is clear from a review of these materials that the Government will seek to elicit opinion testimony from Dr. Cole regarding the safety and efficacy of products manufactured and distributed by the defendant. Among the tracts authored by Dr. Cole, and included in the 3500 material, are "Approach To Review And Rendering My Expert Opinion;" "Avoiding Drug And Medication Rules: Implications For Horseracing;" and, "Effect Of Blood-Doping Agents On Racing Horses." Thus, it is apparent that the Government seeks to call upon Dr. Cole to offer opinion testimony as an expert witness in areas that are forbidden.

First, testimony regarding the content of products manufactured and distributed by Dr. Fishman must be based upon firsthand knowledge or information obtained from qualified sources. Second, any discussion of the content of these items should avoid the ultimate legal conclusion as to whether or not the content of these products, or the manner in which they were labeled, violated the statutes prohibiting adulteration and misbranding. And, third, the Court should not permit testimony regarding Dr. Cole's view of the "safety and efficacy" of these products.

Again, the defendant is not charged with crimes relating to endangering the safety and welfare of animals. The issues at trial will involve (1) whether or not Dr. Fishman was involved in a conspiracy with others named in each of the respective counts that charge him with a crime; (2) whether he was engaged, together with others, in the manufacture, distribution and administration of products that violated the regulatory statutes; and (3) whether Dr. Fishman intended to defraud or mislead customers, regulators or the betting public. *See* 21 U.S.C. §331 and §333(a)(2).

Finally, testimony by Dr. Cole regarding these prohibited subjects will not only be prejudicial to the defendant; but, will be duplicative of testimony sought from other veterinarian-witnesses who will be called to testify in this case.

Thus, Dr. Cole's testimony should, in all respects be precluded.

CONCLUSION

For all the foregoing reasons, we respectfully submit that the evidence described herein should, in all respects, be precluded.

In the alternative, the Government should be required to provide a more extensive summary of the evidence the Government seeks to elicit from its witnesses; and, defense counsel should be given an opportunity to respond to this more detailed proffer of evidence in accordance with Fed.R.Crim.P. Rule 16(a)(1)(G).

Dated: New York, New York
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Respectfully submitted,

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